K123254

Attachment 4

510(k) Summary:

FEB 13 2013

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical
Address: Mileparken 34, DK2730 Herlev, Denmark
Phone: +45 44528100
Fax: +45 44528199
Contact person: Randi Hauerberg, Regulatory Affairs Manager
Date prepared: May 9, 2012

Trade name: Ultrasound Scanner Flex Focus 1202
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
B-K Medical Ultrasound Scanner Flex Focus 1202, K081154
B-K Medical Ultrasound Scanner Pro Focus 2202, K100919

Device description:

Flex Focus 1202 supports the following scanning modes and combinations thereof:
B-mode (incl.Tissue Harmonic Imaging), M-mode, PWD mode, CFM mode, Amplitude (Power) Doppler mode.
The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.
An optional 3-D module can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.
An optional Vector Flow Imaging (VFI) module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

Transducers
Transducers are linear arrays, convex arrays, phased arrays and mechanical sector.
The patient contact materials are biocompatible.
All transducers used together with Flex Focus 1202 are Track 3 transducers.

Acoustic output
The system controlling the Acoustic Output in the modified Flex Focus 1202 is the same as the system in Flex Focus 1200. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Attachment 4

Clinical measurement accuracy
Clinical measurements and calculations are described and accuracies are provided in the User Information.

Thermal, mechanical and electrical safety.
The scanner Flex Focus 1202 has been tested by a recognized Certified Body.

Acoustic Output Reporting
The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 9, 2008"

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body.

Summary of Technological Characteristics – Predicate Device Compared to Modified Device

	Predicate device K081154, Ultrasound scanner Flex Focus 1202	**Predicate device K100919, Ultrasound scanner Pro Focus 2202**	**Modified device (this application), Ultrasound scanner Flex Focus 1202**
Modes of operation Ref.: [1] Appendix G	B, M, PWD, CFM 1) and combinations. Tissue harmonic imaging.	B, M, PWD, CFM 1)+2) and combinations Tissue harmonic imaging.	B, M, PWD, CFM 1)+2) and combinations Tissue harmonic imaging.
Intended Use: Indications For Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)
Features		ECG (not monitoring)	

1) CFM= Color Flow Mapping=Color Doppler and Amplitude (Power) Doppler.

Attachment 4

2) Includes Vector Flow Imaging

Technological characteristics compared to the predicate device
The predicate device has the same major technological characteristics as the subject device described above.
Minor differences consist: Optional Vector Flow Imaging (VFI) module.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 13, 2013

B-K MEDICAL APS
C/O Randi Hauerberg
Regulatory Affairs Manager
MILEPARKEN 34
DENMARK DK-2730

Re: K123254
Trade/Device Name: Ultrasound Scanner Flex Focus
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, and ITX
Dated: January 14, 2013
Received: January 16, 2013

Dear Randi Hauerberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Flex Focus 1202, as described in your premarket notification:

Transducer Model Number 8670

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Robert Ochs at (301) 796-6661.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123254

Device Name: Ultrasound Scanner Flex Focus 1202

Indications for Use:

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD,CWD, Color Doppler, Vector Flow Imaging and combined mode imaging.
Signal analysis and display.
Guidance of biopsy needles, geometrical measurements and calculation of parameters.
Non monitoring ECG for superimposing the ultrasound information.
An optional 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

An optional Vector Flow Imaging (VFI) module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

Clinical applications: Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics, Transrectal, Small organs, Transvaginal, Musculoskeletal.

Details on specific Indication for Use forms

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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Indications for Use

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System:1202
Transducer: 8670

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	Harmonic imaging 2)	Color Doppler	Combined (Specify)	Amplitude Doppler
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal 2)							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E 1)	E
	Small Organ (Specify) 3)	E	E	E	E	E	E 1)	E
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	E	E	E	E	E	E 1)	E
	Musculo-skel. (Superficial)	E	E	E	E	E	E 1)	E
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	E	E	E	E	N[4)]	E 1)	E
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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Indications for Use

Additional Comments: 1) Mode combinations: B+M, B+D, B+C, B+D+C.
(D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler).

2) Includes tissue harmonic imaging.

3) Small part: Breast, testis and penis

4) Vector Flow Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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